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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,323	12/10/2001	Derek J. Hei	282172000404	7855

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EXAMINER	
NAFF, DAVID M	

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1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/016723	Hei et al
Examiner	Group Art Unit
Duffy	1651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 12/10/01.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 58-97 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 58-97 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☒ The ~~proposed~~ drawing ~~correction~~, filed on 12/10/01 are ~~is~~ ☒ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2, 5-8 (file 12/10/01 and 4/23+9/3/02)

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other _____

Office Action Summary

The preliminary amendment of 12/10/01 amended the specification, canceled claims 1-57, and added new claims 58-97.

Claims examined on the merits are 58-97 which are all claims in the application.

Documents 1 and 2 listed on form PTO-1449 of 12/10/01 have been lined through since these documents are listed as documents 67 and 68 on form PTO-1449 of 4/23/02. Document 76 on form PTO-1449 of 4/23/02 has been lined through since this document is also listed as document 3 on form PTO-1449 of 9/3/02.

Specification

The disclosure is objected to because of the following informalities: in the specification at page 42, line 1, "Docket Number 282173000600" should be replaced with the U.S. Patent application number and its current status, and if a patent has issued, the patent number should also be supplied.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 82-84, 87 and 89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 82-84 are confusing by requiring reducing the concentration of a low molecular weight compound in the preamble, and not requiring steps that result in reducing the concentration. Merely treating with a system as previously claimed will not reduce the concentration. Claim 82 should be amended in line 3 by deleting the comma after "61" and inserting -- to bind the low molecular weight compound to the adsorbent particles of the system and reduce the concentration of the low molecular weight compound in the biological composition, --. Claims 83 and 84 should be similarly amended.

Claims 87 and 89 are unclear as to the relationship of the acridine derivative and dye, respectively, to the nucleic acid-binding compound of claim 83. The nucleic acid-binding compound should be required to comprise the acridine derivative and dye as described in the specification. In line 1 of the claims, "low molecular weight" should be replaced with -- nucleic acid-binding --.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to

point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 58-73, 75-78, 81-85 and 87-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley et al (6,319,662) or Lee (6,228,995) in view of Groeger et al (5,605,746) and Samejima (4,160,059).

The claims are drawn to a pathogen-inactivating compound adsorption system for reducing the concentration of a low molecular weight pathogen-inactivating compound in a biological composition. The system contains a housing compatible with the biological composition containing porous adsorbent resin particles having a particle diameter of about 1 μm to about 200 μm immobilized by a matrix. The particles have an affinity for the pathogen-inactivating compound and the system is configured to remove the pathogen-inactivating compound from the biological composition in a flow process, and so that the biological composition treated with the system maintains sufficient biological activity to be suitable for infusion within a human. Also claimed is a method of using the system to treat a biological composition.

Foley et al disclose adding a viral inactivating agent such as a psoralen compound for virus inactivation in a body fluid such as a blood product, and then removing the agent from the blood product with an adsorptive material (col 4, line 42 to col 5, line 61). The adsorptive material may be beads having a particle size of 30-2000 μm, an average

pore diameter of 45-300 angstroms, and a surface area of 150-1600 sq. meters/gram dry bead (col 5, lines 18-20). The beads are enclosed in a container, cartridge or other means for housing the beads (col 2, lines 30-33, and col 4, lines 43-47) through which the blood product passes.

Lee discloses using adsorbent beads to remove viral inactivating agents such as psoralens and psoralen degradation products from a blood product by by passing the blood product through a cartilage containing the beads (col 2, lines 23-37, and Figures 2 and 3). The beads can have a diameter of 0.1 to 2 mm (100-2000 μm) (col 2, line 31).

Groeger et al disclose (col 3, lines 11-22) a fibrous structure containing a composite fiber matrix loaded with adsorbent functional particles such as activated carbon beads (col 5, line 50). The particles may have a size of 1 micron to 3-5 mm depending on the web structure (col 6, lines 12-30). A preferred size for activated carbon particles is about 400 to 500 microns (col 6, line 19). The fibrous structure has applications such as preparing high purity water, and for color or byproduct removal from whiskey and vinegar (col 10, lines 25-27).

Samejima discloses a fiber matrix loaded with an adsorptive material such as activated carbon (col 1, lines 11-39). Activated carbon has a surface area of 800-1800 m^2/gm (col 1, line 29). The adsorptive material may have various uses including purification of tap water (col 1, lines 35-36).

It would have been obvious to provide the adsorbent beads of Foley et al or Lee within a matrix as taught by Groeger et al and Samejima to obtain an expected advantage of the matrix holding the beads to

facilitate handling of the beads and separation of the beads from a blood product. The container or cartridge of Foley et al and Lee which contains the beads provides a housing for the beads. The adsorbent beads in the container or cartridge of Foley et al and Lee are used to treat a blood product to produce a blood product for infusing into a patient (Foley et al (col 3, lines 5-15) and Lee (col 3, lines 35-36). A blood product treated as disclosed by Foley et al or Lee inherently has sufficient activity to be infused into a human as claimed. When using a matrix such as a fibrous matrix to hold the beads, it would have been obvious to use a matrix that results in a blood product suitable for infusion into a human since this is an objective of Foley et al and Lee. Furthermore, the particle-containing matrix of Groeger et al or Samejima can be used for purifying water or liquids to be consumed by a human, and such a matrix would appear to be capable of providing a blood product suitable for infusing into a human. The conditions of dependent claims would have been matters of obvious choice within the skill of the art in view of the disclosures of the references and knowledge common in the art.

Claim Rejections - 35 USC § 103

Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 58-73, 75-78, 81-85 and 87-97 above, and further in view of Davankov et al.

The claim requires the adsorbent resin particles to be hypercrosslinked.

Davankov et al disclose the use of hypercrosslinked polystyrene particles as an advantageous adsorbent to remove toxicants from blood.

It would have been obvious to use the hypercrosslinked polystyrene particles of Davankov et al for their expected advantage as the adsorbent beads of Foley et al or Lee when the beads are in a matrix as suggested by Groeger et al and Samejima.

Claim Rejections - 35 USC § 103

Claims 79 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 58-73, 75-78, 81-85 and 87-97 above, and further in view of Horowitz et al (6,294,361).

The claims require the resin particles to have affinity for a nucleic acid-binding compound having an electrophilic group that reacts with a nucleophilic group of a quencher.

Horowitz et al discloses (col 7, line 57 to col 8, line 16) the use of a quencher when inactivating a virus in blood with a psoralen compound.

When providing the beads of Foley et al or Lee in a matrix for removing a viral-inactivating agent such as a psoralen compound from a blood product as set forth above, it would have been obvious use a quencher for its expected function as taught by Horowitz et al, and the reacting of an electrophilic group of the psoralen compound with a nucleophilic group of the quencher would have been inherent.

Claim Rejections - 35 USC § 103

Claim 86 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 58-73, 75-78, 81-85 and 87-97 above, and further in view of Wollowitz et al (5,593,823).

The claim requires specific psoralen compounds as the pathogen-inactivating compound.

Wollowitz et al disclose psoralen compounds that have improved pathogen-inactivating activity in blood that can be the same as presently claimed. For example, see the paragraph bridging cols 4 and 5, and col 65, lines 35-51.

When providing the beads of Foley et al or Lee in a matrix for removing a viral-inactivating agent from a blood product as set forth above, it would have been obvious to use the psoralen compounds of Wollowitz et al as the psoralen compound to obtain their improved pathogen inactivating activity.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 58-85 and 87-97 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-52 of copending Application No. 09/972,323 in view of Foley et al or Lee.

The claimed invention, Foley et al and Lee are described above.

The claims of the copending application require a device for reducing the concentration of a low molecular weight compound in a biological composition wherein the device comprises a matrix containing adsorbent particles of about 100 μm to 1500 μm diameter for use in a batch process. The low molecular weight compound may be an acridine derivative, a psoralen derivative or a dye, and the resultant treated biological composition can be suitable for infusion.

It would have been obvious to enclose the matrix and adsorbent particles of the device of the copending application claims in a flow through housing as suggested by Foley et al or Lee using adsorbent beads in a flow through housing to obtain continuous flow when removing a viral inactivating agent from a blood product.

This is a provisional obviousness-type double patenting rejection.

Double Patenting

Claim 86 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-52 of copending Application No. 09/972,323 in view of Wollowitz et al.

Wollowitz et al would have suggested psoralen compounds as presently claimed as the low molecular weight compound of the copending applications claims for the type of reasons set forth above when applying Wollowitz et al.

Double Patenting

Claims 58-97 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53-105 of copending Application No. 10/011,202 in view of Foley et al or Lee.

The claimed invention, Foley et al and Lee are described above.

The claims of the copending application are drawn to a pathogen-inactivating compound adsorption system for reducing the concentration of a low molecular weight pathogen-inactivating compound in a biological composition containing cellular elements. The system contains a housing compatible with the biological composition containing porous adsorbent particles having a particle diameter of about 100 μm to about 1500 μm immobilized by a matrix. The particles have an affinity for the pathogen-inactivating compound and the system is configured to remove the pathogen-inactivating compound from the biological composition in a batch

process, and so that the cellular elements of the biological composition treated with the system maintain sufficient biological activity so that the biological composition is suitable for infusion within a human. Also claimed is a method of using the system to treat a biological composition.

It would have been obvious to provide the matrix and adsorbent particles in the housing of the system of the copending application claims for flow through the housing instead of for a batch process as suggested by Foley et al or Lee using adsorbent beads in a flow through housing to obtain continuous flow when removing a viral inactivating agent from a blood product.

This is a provisional obviousness-type double patenting rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651

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